

**REMARKS**

This Amendment is filed in response to the non-final Office Action dated October 2, 2008, and is respectfully submitted to be fully responsive to the rejections raised therein. Accordingly, favorable reconsideration on the merits and allowance are respectfully requested.

In the present Amendment, claims 1-3 and 8 have been canceled.

Claims 4-7 were canceled previously in the Preliminary Amendment filed May 22, 2008.

Claim 9 has been amended by deleting the term “preventing.” Claim 11 has been amended to bring it into a more suitable format for referring other claims.

No new matter has been added. Entry of the Amendment is respectfully submitted to be proper. Upon entry of the Amendment, claims 9-11 will be all the claims pending in the application.

**I. Response to Rejection Under 35 U.S.C. § 112, First Paragraph**

Claims 1-3 and 8-11 are rejected under 35 U.S.C. § 112, first paragraph. According the Examiner, the specification, while being enabling for the *treatment* of chronic pelvic pain syndrome, does not reasonably provide enablement for the “*prevention* of chronic pelvic pain syndrome”.

Applicants traverse and respectfully request that the rejection be withdrawn in view of the amendments to the claims. Specifically, without acquiescing, Applicants have deleted the term “preventing” from the preamble of the claim.

**II. Response to Rejection Under 35 U.S.C. § 102(e)**

Claims 1-3 and 8 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 6,987,129 (Mak).

Applicants respectfully submit that the rejection is moot in view of the amendments to the claims, wherein claims 1-3 and 8 have been canceled. Withdrawal of the this rejection is requested.

**III. Response to Rejection Under 35 U.S.C. § 103(a)**

Claims 9-11 are rejected under 35 U.S.C. § 103 (a) as assertedly being unpatentable over Mak. According to the Examiner, Mak teaches methods for treating a variety of disorders including interstitial cystitis using a variety of compounds including phosphodiesterase inhibitors. Additionally, the Examiner asserts that Mak teaches that the phosphodiesterase inhibitor includes roflumilast and ariflo (SB207499) which are phosphodiesterase IV inhibitors.

Applicants respectfully traverse.

Applicants respectfully submit that Mak lists combinations of many compositions varying in mechanisms, which are expected to mainly have functions to dilate smooth muscles and many diseases related to urinary tract. However, Mak does not specifically describe the experimental results which show the effects of these compositions on each disease, especially on chronic pelvic pain syndrome (interstitial cystitis). In particular, Mak does not describe the experimental results which show the effects of PDE 4 inhibitors such as roflumilast and cilomilast on chronic pelvic pain syndrome (interstitial cystitis). Therefore, there is no guidance

in Mak, which directs or motivates one skilled in the art towards the specific combination of a PDE 4 inhibitor and chronic pelvic pain syndrome (interstitial cystitis), among numerous possible combinations of compositions and diseases suggested by Mak. Even assuming there was market pressure to find a treatment of chronic pelvic pain syndrome, Mak provides practically indefinite number of possible solutions, instead of finite number of identified, predictable solutions. From the reading of Mak, one skilled in the art would not have good reason to pursue the numerous possible combinations as a treatment of chronic pelvic pain syndrome within his or her technical grasp. Neither the Examiner provides scientific or technical explanations as to why one skilled in the art would have been directed to the specific combination (use of roflumilast and cilomilast to treat chronic pelvic pain syndrome) among the numerous possibilities. Therefore, the method of treating chronic pelvic pain syndrome (interstitial cystitis) using a PDE 4 receptor is not obvious to one skilled in the art.

Accordingly, Applicants respectfully submit that claims 9-11 are not rendered obvious over Mak. Withdrawal of the rejection based on Mak is respectfully requested.

#### **IV. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Sunhee Lee/

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

**65565**

CUSTOMER NUMBER

Date: December 29, 2008

---

Sunhee Lee  
Registration No. 53,892